

Package leaflet: Information for the recipient

COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection tozinameran

This medicinal product has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines & Healthcare products Regulatory Agency. It does not have a marketing authorisation, but this temporary authorisation grants permission for the medicine to be used for active immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals aged 12 years of age and over.

Reporting of side effects

As with any new medicine in the UK this product will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What COVID-19 mRNA Vaccine BNT162b2 is and what it is used for
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1. What COVID-19 mRNA Vaccine BNT162b2 is and what it is used for

COVID-19 mRNA Vaccine BNT162b2 is a vaccine used for active immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus.

COVID-19 mRNA Vaccine BNT162b2 is given to adults and adolescents from 12 years.

The vaccine triggers the body's natural production of antibodies and stimulates immune cells to protect against COVID-19 disease.

2. What you need to know before you receive COVID-19 mRNA Vaccine BNT162b2

COVID-19 mRNA Vaccine BNT162b2 should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you have an allergic reaction. It can be life-threatening.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if you have:

- ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given COVID-19 mRNA Vaccine BNT162b2 in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- a severe illness with high fever
However, a mild fever or upper airway infection, like a cold, are not reasons to delay vaccination.
- a weakened immune system, such as due to HIV infection, or are on a medicine that affects your immune system
- a bleeding problem, bruise easily or use a medicine to inhibit blood clotting

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with COVID-19 mRNA Vaccine BNT162b2 (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, COVID-19 mRNA Vaccine BNT162b2 may not fully protect all those who receive it. No data are currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

If you are immunocompromised and receive an additional dose of mRNA Vaccine BNT162b2, it may still not provide full immunity to COVID-19 and you should continue to maintain physical precautions to help prevent COVID-19.

Children

COVID-19 mRNA Vaccine BNT162b2 is not recommended for children under 12 years.

Other medicines and COVID-19 mRNA Vaccine BNT162b2

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Driving and using machines

COVID-19 mRNA Vaccine BNT162b2 has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 'Possible side effects' may temporarily affect the ability to drive or use machines. Do not drive or operate machinery until you are sure that you are not affected.

COVID-19 mRNA Vaccine BNT162b2 contains sodium and potassium

This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'. This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How COVID-19 mRNA Vaccine BNT162b2 is given

COVID-19 mRNA Vaccine BNT162b2 is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 2 injections, given at least 21 days apart.

If you receive one dose of COVID-19 mRNA Vaccine BNT162b2, you should receive a second dose of the same vaccine at least 21 days later to complete the vaccination series. Protection against COVID-19 disease may not be maximally effective until at least 7 days after the second dose.

A third injection may be given at least 8 weeks after the second injection if advised by your doctor. This may also be if your first two doses were with another COVID-19 vaccine.

If you have any further questions on the use of COVID-19 mRNA Vaccine BNT162b2, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, COVID-19 mRNA Vaccine BNT162b2 can cause side effects, although not everybody gets them.

Most side effects are mild or moderate and go away within a few days of appearing. If side effects such as pain and/or fever are troublesome, they can be treated by medicines for pain and fever such as paracetamol.

Side effects may occur with following frequencies:

Very common: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea
- fever

Common: may affect up to 1 in 10 people

- redness at injection site
- nausea
- vomiting

Uncommon: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- decreased appetite
- excessive sweating
- night sweats

Rare side effects: may affect up to 1 in 1,000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10,000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)

Some people have reported a sudden feeling of cold with shivering/shaking accompanied by a rise in temperature, possibly with sweating, headache (including migraine-like headaches), nausea, muscle aches and feeling unwell, starting within a day of having the vaccine and usually lasting for a day or two.

If your fever is high and lasts longer than three days, or you have other persistent symptoms, this might not be due to side effects of the vaccine and you should seek appropriate medical advice according to your symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. When completing a report please include the vaccine brand and batch/Lot number if available.

Alternatively, side-effects of concern in association with Pfizer BioNTech COVID-19 mRNA vaccine BNT162b2 can be reported to Pfizer Medical Information on 01304 616161 or via www.pfizersafetyreporting.com.

Please do not report the same side-effect(s) to both systems as all reports will be shared between Pfizer and MHRA (in an anonymized form) and dual reporting will create unnecessary duplicates. By reporting side effects, you can help provide more information on the safety of this vaccine.

5. How to store COVID-19 mRNA Vaccine BNT162b2

Do not use this medicine after the expiry date which is stated on the box and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -80°C to -60°C.

Store in the original package in order to protect from light.

After thawing, the vaccine should be diluted and administered by a healthcare professional and used within 6 hours. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 1 month (31 days) at 2°C to 8°C. Any unused vaccine should be discarded.

6. Contents of the pack and other information

What COVID-19 mRNA Vaccine BNT162b2 contains

- The active substance is tozinameran.
After dilution, the vial contains 6 doses, of 0.3 mL with 30 micrograms tozinameraneach.

This vaccine contains polyethylene glycol/macrogol (PEG) as part of ALC-0159

- The other ingredients are:
 - ALC-0315 = (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate),
 - ALC-0159 = 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide,
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine,
 - cholesterol,
 - potassium chloride,
 - potassium dihydrogen phosphate,
 - sodium chloride,
 - disodium hydrogen phosphate dihydrate,
 - sucrose
 - water for injections

What COVID-19 mRNA Vaccine BNT162b2 looks like and contents of the pack

The vaccine is a white to off-white solution provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 195 vials

Manufacturer(s)

BioNTech Manufacturing GmbH
Kupferbergterrasse 17-19
55116 Mainz, Germany

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